**IN THE UNITED STATES**
**PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| APPLICANT: | Takeda Pharmaceutical Co., Ltd. |
| U.S. PATENT NO. | 6,462,058 |
| ISSUED: | October 8, 2002 |
| TO: | FUJISHIMA ET AL. |
| FOR: | BENZIMIDAZOLE COMPOUND CRYSTAL |
| FROM: | Serial No. 09/674624 |
| FILED: | June 15, 2000 |
| EXTENSION FILED: | March 26, 2009 |
| ATTORNEY DOCKET NO. | 04164.0012USTE |

DATE: April 29, 2010

CERTIFICATE UNDER 37 CFR 1.10:
"Express Mail" mailing label number: EM088199558US
Date of Deposit: April 29, 2010
I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450.

By: Linda Binion
Name: Linda Binion

**SUBMISSION OF SUPPLEMENTAL APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156 TO APPLICATION FILED ON MARCH 26, 2009**

Mail Stop: Patent Extension
Commissioner of Patents
Patent Extension
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Applicant Takeda Pharmaceutical Company Limited hereby submits this supplemental application for extension of patent term for the above identified patent due to a change of the name of the Approved Product from "Kapidex" to "Dexilant" in April 2010. The actual product has not been changed.

Takeda Pharmaceutical Company Limited ("Takeda" or "Applicant"), a corporation organized and existing under the laws of Japan, having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka-shi, Osaka, Japan, represents that it is the owner and assignee of the entire interest in and to the above-identified patent. Applicant was formerly called Takeda Chemical Industries Limited, which was the original assignee of U.S. Patent No. 6,462,058, and changed its name to Takeda Pharmaceutical Company Limited as of June 29, 2004. Based on this change of the corporate name, the change of name of the assignee of the above-identified patent to Applicant was recorded on January 19, 2005. A copy of the assignment of U.S. Patent No. 6,462,058 to Takeda Chemical Industries Limited (Exhibit A) and a copy of the documents filed for the change of the corporate name to Takeda Pharmaceutical Company Limited (Exhibit B) are attached hereto.

The NDA application of the Approved Product for the regulatory review by the United States Food and Drug Administration ("FDA") was filed by TAP Pharmaceutical Products Inc., which had been a 50-50 joint venture corporation between Takeda Pharmaceutical Co., Ltd. and Abbott Laboratories and had been a licensee of Applicant for the Approved Product. TAP Pharmaceutical Products Inc. was merged with Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc. as of July 1, 2008 and accordingly, Takeda Pharmaceuticals North America, Inc., which is a subsidiary of Applicant, is the owner of the NDA approval of the Approval Product. A copy of the NDA approval is attached hereto as Exhibit C.

Applicant hereby petitions for extension of U.S. Patent No. 6,462,058 under 35 U.S.C. §156(d) and 37 C.F.R. §1.740 and states in part thereof as follows:

**(1) A COMPLETE IDENTIFICATION OF THE APPROVED PRODUCT AS BY APPROPRIATE CHEMICAL AND GENERIC NAME, PHYSICAL STRUCTURE OR CHARACTERISTICS**

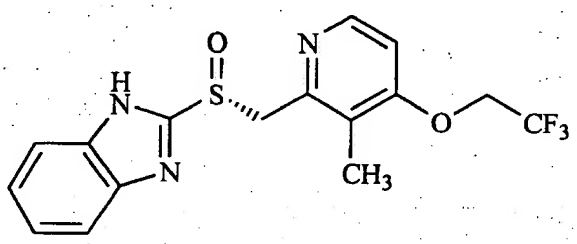
The name of the Approved Product "Kapidex" in the above identified application submitted on March 26, 2009 has been changed to "Dexilant" since April 2010.

The chemical and generic name, physical structure, or characteristics of a new drug Dexilant (hereinafter sometimes referred to as "Approved Product"), which is approved by the FDA, are as follows:

The generic name of the active ingredient contained in the Approved Product is dexlansoprazole.

The chemical name of dexlansoprazole is:
2-[(R)-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]-1H-benzimidazole.

The chemical structure of dexlansoprazole is:




with a molecular formula of $C_{16}H_{14}F_3N_3O_2S$ and a molecular weight of 369.36 (based on the 2001 International Union of Pure and Applied Chemistry [IUPAC] Atomic Weight of the Elements). The Approved Product Dexilant includes a crystal form of dexlansoprazole. The data of Dexilant in the NDA submitted to the FDA were produced by using the same crystalline form of dexlansoprazole as that of claim 1 in U.S. Patent No. 6,462,058.

**(2) A COMPLETE IDENTIFICATION OF THE FEDERAL STATUTE INCLUDING THE APPLICABLE PROVISION OF LAW UNDER WHICH THE REGULATORY REVIEW OCCURRED**

An application for commercial marketing approval of Dexilant in the U.S. was filed pursuant to §505 (b) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §355(b)) and reviewed under this section of the law.

**(3) AN IDENTIFICATION OF THE DATE ON WHICH THE PRODUCT RECEIVED PERMISSION FOR COMMERCIAL MARKETING OR USE UNDER THE PROVISION OF LAW UNDER WHICH THE APPLICABLE REGULATORY REVIEW PERIOD OCCURRED**

The commercial marketing of the Approved Product was approved on January 30, 2009 by the FDA. A copy of the FDA approval is attached hereto as Exhibit C.

**(4) IN THE CASE OF A DRUG PRODUCT, AN IDENTIFICATION OF EACH ACTIVE INGREDIENT IN THE PRODUCT AND AS TO EACH ACTIVE INGREDIENT, A STATEMENT THAT IT HAS NOT BEEN PREVIOUSLY APPROVED FOR COMMERCIAL MARKETING OR USE UNDER THE FDCA, THE PUBLIC HEALTH SERVICE ACT, OR THE VIRUS-SERUM-TOXIN ACT, OR A STATEMENT OF WHEN THE ACTIVE INGREDIENT WAS APPROVED FOR COMMERCIAL MARKETING OR USE (EITHER ALONE OR IN COMBINATION WITH OTHER ACTIVE INGREDIENTS), THE USE FOR WHICH IT WAS APPROVED, AND THE PROVISION OF LAW UNDER WHICH IT WAS APPROVED**

The Approved Product Dexilant is a sustained release formulation in a capsule using a crystalline form of dexlansoprazole as an active ingredient. This active ingredient has not been approved previously for the commercial marketing or use under the FDCA, the Public Health service Act, or the Virus-Serum-Toxin Act. Lansoprazole, a racemate of the active ingredient of the Approved Product, has been approved previously.

**(5) A STATEMENT THAT THE APPLICATION IS BEING SUBMITTED WITHIN THE SIXTY DAY PERIOD PERMITTED FOR SUBMISSION PURSUANT TO § 1.720(f) AND AN IDENTIFICATION OF THE DATE OF THE LAST DAY ON WHICH THE APPLICATION COULD BE SUBMITTED**

The sixty (60)-day period began on the approval date of the Approved Product January 30, 2009 and will expire on March 30, 2009. Accordingly, this application is being submitted within the 60-day period pursuant to 37 C.F.R. §1.720(f).

**(6) A COMPLETE IDENTIFICATION OF THE PATENT FOR WHICH AN EXTENSION IS BEING SOUGHT BY THE NAME OF THE INVENTOR, THE PATENT NUMBER, THE DATE OF ISSUE, AND THE DATE OF EXPIRATION**

The information of patent for which this application is submitted is as follows:

| | |
|---|---|
| U.S. Patent No.: | 6,462,058 |
| Inventors: | Akira Fujishima |
| | Isao Aoki |

| | |
|---|---|
| | Keiji Kamiyama |
| Title: | BENZIMIDAZOLE COMPOUND CRYSTAL |
| Date of issue: | October 8, 2002 |
| Date of expiration: | June 15, 2020 absent the extension |

U.S. Patent No. 6,462,058 was granted on the 8th day of October2002 to Akira Fujishima, Isao Aoki, and Kenji Kamiyama and was assigned to Takeda Chemical Industries Ltd. Takeda Chemical Industries Ltd. changed the corporate name to Takeda Pharmaceutical Co., Ltd. as of June 29, 2004, and the name change to Takeda Pharmaceutical Co. Ltd. was recorded in the United Patent Trademark Office on January 19, 2005, at Reel 015612, Frame 0101. A copy of the assignment to Takeda Chemical Industries Ltd. and the change of the corporate name are attached hereto as Exhibits A and B, respectively.

**(7) A COPY OF THE PATENT FOR WHICH AN EXTENSION IS BEING SOUGHT, INCLUDING THE ENTIRE SPECIFICATION (INCLUDING CLAIMS) AND DRAWINGS**

A copy of the U.S. Patent No. 6,462,058, for which the extension is being sought, including the entire specification (including claims) is attached hereto as Exhibit D.

**(8) A COPY OF DISCLAIMER, CERTIFICATE OF CORRECTION, RECEIPT OF MAINTENANCE FEE PAYMENT, OR REEXAMINATION CERTIFICATE ISSUED IN THE PATENT**

U.S. Patent No. 6,462,058, for which this application of the patent term extension is filed, is not subject to terminal disclaimers over other U.S. Patent or U.S. Patent applications.

No certificate of correction or reexamination certificate has been issued.

A copy of documents showing payment of the maintenance fee payment for U.S. Patent No. 6,462,058 is attached hereto as Exhibit E.

**(9) A STATEMENT THAT THE PATENT CLAIMS THE APPROVED PRODUCT, OR A METHOD OF USING OR MANUFACTURING THE APPROVED PRODUCT, AND A SHOWING WHICH LISTS EACH APPLICABLE PATENT CLAIM AND DEMONSTRATES THE MANNER IN WHICH AT LEAST ONE SUCH PATENT CLAIM READS**

U.S. Patent No. 6,462,058 claims, dexlansoprazole, which is an active ingredient for the Approved Product, having a particular crystalline form in claim 1, a pharmaceutical composition including the particular crystalline form of dexlansoprazole in claim 1, i.e., the Approved Product, in claim 3, a method of manufacturing the Approved Product including dexlansoprazole having the particular crystalline form for an intended use in claim 5, and a method of using the Approved Product including dexlansoprazole having the particular crystalline form for the intended use in claim 6, as shown in Exhibit F. The claimed particular crystalline form in claim 1 is the same crystalline form as that used for the NDA of the Approved Product (see Exhibit G). Please note that the X-ray powder diffraction of dexlansoprazole in the Approved Product was measured by different equipment under different measuring conditions from those used to obtain data for U.S. Patent No. 6,462,058 and might include minor experimental deviations.

**(10) A STATEMENT OF THE RELEVANT DATES AND INFORMATION PURSUANT TO 35 U.S.C. 156(g) IN ORDER TO ENABLE THE SECRETARY OF HEALTH AND HUMAN SERVICES OR THE SECRETARY OF AGRICULTURE, AS APPROPRIATE, TO DETERMINE THE APPLICABLE REGULATORY REVIEW PERIOD**

The information required by 37 C.F.R. §1.740(a)(10) for a patent claiming the Approved Product, a human drug Dexilant, is as follows:

(A) Effective date of the investigational new drug (IND) application and the IND number:

Effective date of IND Application: July 2, 2004

IND number: 69,927

(B) Effective date on which a new drug application (NDA) was initially filed and the NDA number:

Application date of NDA: December 28, 2007

NDA number: 22-287

(C) Date on which the NDA No. 22-287 was approved is January 30, 2009.

(11) **A BRIEF DESCRIPTION OF THE SIGNIFICANT ACTIVITIES UNDERTAKEN BY THE MARKETING APPLICANT DURING THE APPLICABLE REGULATORY REVIEW PERIOD WITH RESPECT TO THE APPROVED PRODUCT AND THE SIGNIFICANT DATES APPLICABLE TO SUCH ACTIVITIES**

A brief description of the significant activities undertaken by the applicant of the commercial marketing approval Takeda during the applicable regulatory period for the Approved Product and the significant dates applicable to such activities are shown in Exhibit H attached hereto.

(12) **A STATEMENT THAT IN THE OPINION OF THE APPLICANT THE PATENT IS ELIGIBLE FOR THE EXTENSION AND A STATEMENT AS TO THE LENGTH OF EXTENSION CLAIMED, INCLUDING HOW THE LENGTH OF EXTENSION WAS DETERMINED**

Applicant is of the opinion that U.S. Patent No. 6,462,058 is eligible for the patent term extension under 35 U.S.C. §156 because the requirements of 35 U.S.C. §156 (a) and (c)(4) have been satisfied as follows:

(a) 35 U.S.C. §156(a)

U.S. Patent No. 6,462,058 claims dexlansoprazole, which is an active ingredient of a human drug Dexilant, having a particular crystalline form as defined in 37 C.F.R. §1.710, in claim 1 and a pharmaceutical composition including the particular crystalline form of dexlansoprazole, i.e., the Approved Product, in claim 3.

(b) 35 U.S.C. §156(a)(1)

U.S. Patent No. 6,462,058 has not yet expired as of the date of submission of this application.

(c) 35 U.S.C. §156(a)(2)

The term of U.S. Patent No. 6,462,058 has never been extended under 35 U.S.C. §156(e)(1).

(d) 35 U.S.C. §156(a)(3)

This application for extension of U.S. Patent No. 6,462,058 is being submitted by the owner of record Takeda Pharmaceutical Co., Ltd. through their attorneys in accordance with the requirements of 35 U.S.C. §156(d)(1) through (4).

(e) 35 U.S.C. §156(a)(4)

The Approved Product Dexilant has been subject to a regulatory review period under §505 of the FDCA (21 U.S.C. §355) before its commercial marketing or use.

(f) 35 U.S.C. §156(a)(5)(A)

The permission for the commercial marketing or use of the Approved Product after such regulatory review period is the first permitted commercial

marketing or use of the Approved Product and the active ingredient of the Approved Product dexlansoprazole under §505 of the FDCA (21 U.S.C. §355).

(g) 35 U.S.C. §156(c)(4)

To the date of this application, there is no other U.S. patent that has been extended under 35 U.S.C. §156(e)(1) for the same regulatory review period for the Approved Product. Applicant acknowledges that applications for extension of U.S. Patent Nos. 6,664,276 and 6,939,971 are being filed based on the same regulatory review period, and confirms that Applicant will elect one of the three for grant.

Applicant further is of the opinion that U.S. Patent No. 6,462,058 is entitled to the patent term extension under 35 U.S.C. §156 for the length of 959 days extended from June 15, 2020 as determined pursuant to 37 C.F.R. §1.775 by the following:

(a) 37 C.F.R. §1.775(b)

The number of days in the period beginning on the effective date of the IND application for the Approved Product July 2, 2004 and ending on December 28, 2007, which is the date of the initial NDA application for the Approved Product was filed under §505(b) of the FDCA, is 1275 days ("Period (c)-1" as defined under 35 U.S.C. §156(g)(1)(B)(i)).

The number of days in the period beginning on the date of the NDA application for the Approved Product December 28, 2007 and ending on the approval date of the NDA January 30, 2009 is 400 days ("Period (c)-2" as defined under 35 U.S.C. §156(g)(1)(B)(ii)).

(b) 37 C.F.R. §1.775(d)(1)

The term of extension of U.S. Patent No. 6,462,058 is determined by subtracting the number of days of (i)-(iii) below from the total period of Period (c)-1 and Period (c)-2.

(i) The number of days in Periods (c)-1 and (c)-2 on and before the issue date of U.S. Patent No. 6,462,058 October 8, 2002 is zero (0) day.

(ii) The number of days in Period (c)-1 and (c)-2 during which Applicant did not act with due diligence is zero (0) day.

(iii) One-half (1/2) the number of days remaining in the Period (c)-1 after reduced by the days of (b)-(i) and (ii) above is 637 days.

Accordingly, the extension period is 1038 days, calculated by subtracting 637 days from 1675 days (Periods (c)-1 and (c)-2: 1275 + 400 days).

(c) 37 C.F.R. §1.775(d)(2)

U.S. Patent No. 6,462,058 filed on June 15, 2000 is not subject to a terminal disclaimer. The extended expiration date of U.S. Patent No. 6,462,058 obtained by adding 1038 days to June 15, 2020 is April 19, 2023.

(d) 37 C.F.R. §1.775(d)(3)

The extended date calculated by adding 14 years to the NDA approval date January 30, 2009 is January 30, 2023.

(e) 37 C.F.R. §1.775(d)(4)

The earlier date of the extended expiration dates of U.S. Patent No. 6,462,058 in (c) and (d) above is January 30, 2023.

(f) 37 C.F.R. §1.775(d)(5)

The earlier date of the extended expiration dates of U.S. Patent No. 6,462,058 in (e) and the date June 15, 2025 calculated by adding five (5) years to the current expiration date June 15, 2020 is January 30, 2023.

In light of the (a)-(e) above, Applicant is in the opinion that the extended expiration date of U.S. Patent No. 6,462,058 should January 30, 2023, i.e., 959 days or 2 years and 229 days from the date of the current expiration date June 15, 2020.

**(13) A STATEMENT THAT APPLICANT ACKNOWLEDGES A DUTY TO DISCLOSE TO THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE AND THE SECRETARY OF HEALTH AND HUMAN SERVICES ANY INFORMATION WHICH IS MATERIAL TO THE DETERMINATION OF ENTITLEMENT TO THE EXTENSION SOUGHT**

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and to the Secretary of Health and Human Services any information that is material to the determination of entitlement to the extension of U.S. Patent No. 6,462,058 being sought.

**(14) THE PRESCRIBED FEE FOR RECEIVING AND ACTING UPON THE APPLICATION FOR EXTENSION**

The filing fee of the application for extension was paid upon filing the original application on March 26, 2009. Please charge Deposit Account No. 50-3478 any additional fees or credit overpayment to Deposit Account No. 50-3478.

**(15) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF THE PERSON TO WHOM INQUIRIES AND CORRESPONDENCE RELATING TO THE APPLICATION FOR PATENT TERM EXTENSION ARE TO BE DIRECTED**

Please address all inquires and correspondence relating to this application for patent term extension to:

Douglas P. Mueller
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

**(16) THE APPLICATION UNDER THIS SECTION MUST BE ACCOMPANIED BY TWO ADDITIONAL COPIES OF SUCH APPLICATION**

No additional copies of this supplemental application are attached hereto as instructed.

Respectfully submitted,



HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

Dated: April 29, 2010

By: _____
Douglas P. Mueller
Reg. No. 30,300

DPM/my